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Dated: August 18, 2004

Signature:

Shawn P. Foley
(Shawn P. Foley)

Docket No.:
CELLTH 3.0-003 CONT CONT XV
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Warrell et al.

Application No.: 10/759,882

Group Art Unit: 1616

Filed: January 16, 2004

Examiner: A. N. Pryor

For: PROCESS FOR PRODUCING ARSENIC
TRIOXIDE FORMULATIONS AND
METHODS FOR TREATING CANCER USING
ARSENIC TRIOXIDE OR MELASOPROL

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REQUEST FOR CONSIDERATION OF INFORMATION UNDER 37 CFR § 1.97 (C)

Dear Sir:

It is respectfully requested that the references cited in the enclosed form be considered pursuant to 37 C.F.R. § 1.97(c). Please charge Deposit Account No. 12-1095 in the amount of \$180.00 pursuant to 37 C.F.R. § 1.17(p). In the event that any additional fee is due in connection with the present request, the same should be charged to our Deposit Account No. 12-1095.

Dated: August 18, 2004

Respectfully submitted,

By *Shawn P. Foley*
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INFORMATION DISCLOSURE STATEMENT

Dear Sir:

It is respectfully requested that the references listed on the enclosed form be made of record and considered with respect to the above-referenced U.S. patent application. A copy of each reference was of record in United States Patent 6,723,351, the benefit of which is claimed under §120. Submission of the present Information Disclosure Statement should not be taken as an admission that the cited references are legally available prior art or that the same are pertinent or material.

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08/25/2004 GWORDOF1 00000042 121095 10759882

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Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known		
				Application Number	10/759,882	
Sheet		1	of	5	Attorney Docket Number	CELLTH 3.0-003 CONT CONT XV
					Filing Date	January 16, 2004
					First Named Inventor	Raymond P. Warrell, Jr.
					Art Unit	1616
					Examiner Name	A. N. Pryor

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	AA**	US-132,275-B1	10-15-1872	Gettings	
	AB**	US-232,807	10-05-1886	Dennett	
	AC**	US-3,700,498	10-24-1972	Kanazawa et al.	
	AD**	US-4,497,780	02-05-1985	Barin et al.	
	AE**	US-5,759,837	06-02-1998	Kuhajda et al.	
	AF**	US-2002/0183385	12-05-2002	Ellison et al.	
	AG**	US-6,720,011	04-13-2004	Zhang, Ting-Dong	
	AH**	US-6,770,304	08-03-2004	Warrell et al.	
	AI**	US-2003/0099719	05/2003	Warrell et al.	
	AJ**	US-6,723,351	04-20-2004	Warrell et al.	
	AK**	US-6,773,792	05-11-2004	Lu	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
	BA	JP-51-88620	03-08-1976			
	BB	WO-95/01789	01-19-1995			
	BC	CN-1133725	10-23-1996			
	BD	CN-1131037	09-18-1996			
	BE	CN-1122700	05-22-1996			
	BF	CN-1081104	01-26-1994			
	BG	CN-1119113	03-27-1996			
	BH	CN-1061908	06-17-1992			
	BI	CN-1121807	05-08-1996			
	BJ	CN-1079391	12-15-1993			
	BK	WO-94/02103	02-03-1994			
	BL	FR-2 539 993	03-31-1994			
	BM	DE-43 17 331	12-01-1994			
	BN	WO-95/22336	08-24-1995			
	BO	LV-11667	06-20-1997			
	BP	WO-94/02108	02-03-1994			

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. **CITE NO.: Those patent(s) or publication(s) which are marked with an double asterisk (**) next to the Cite No. are not supplied because they were previously cited by or submitted to the Office in a prior application relied upon in this application for an earlier filing date under 35 U.S.C. 120. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	CA	CUTLER et al., Article IV, American Journal of the Medical Sciences, pp. 74-84, January 1878	
	CB	FORKNER et al., "Arsenic as a therapeutic agent in chronic myelogenous leukemia", Jour.	

Examiner Signature		Date Considered	
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				Art Unit	1616
				Examiner Name	A. N. Pryor
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Sheet	2	of	5		

		A.M.A. 97(1):3-5, 1931	
CC		STEPHENS, et al., "The therapeutic effect of solution of potassium arsenite in chronic myelogenous leukemia", University of Rochester, pp. 1488-1502, 1936	
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CS		LI et al., "Traditional Chinese and Western Medicine in the Treatment of 27 Patients with Malignant Lymphoma", Chinese J. Oncology, 10:61-62, 1988	
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CY		"Inorganic Arsenic Compounds Other Than Arsenic Health and Safety Guide", Health and Safety Guide No. 70," WHO, Geneva 1992	
CZ		"Xionghuang, Realgar", Chinese Pharmacopoeia (I), Guangdong Science and Technology Publishing House, China, pp. 298-299, 1995	
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CB1		ANDRE et al., "The PML and PML/RAR α Domains: From Autoimmunity to Molecular Oncology and From Retinoic Acid to Arsenic", Experimental Cell Research, 229:253-260, 1996 ©Academic Press, Inc. 1996	
CC1		Chemical Abstract, 63-Pharmaceuticals 11:317, 111:219272j and 111:219276p, 1987-1991	

Examiner Signature		Date Considered	
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				Art Unit	1616
				Examiner Name	A. N. Pryor
				Attorney Docket Number	CELLTH 3.0-003 CONT CONT XV
Sheet	3	of	5		

CD1		CHEN et al., "In Vitro Studies on Cellular and Molecular Mechanisms of Arsenic Trioxide (As ₂ O ₃) in the Treatment of Acute Promyelocytic Leukemia: As ₂ O ₃ induces NB ₄ Cell Apoptosis with Down Regulation of Bcl-2 Expression and Modulation of PML-RAR α /PML proteins", Blood 88(3): 1052-1061, Aug. 1996. ©American Society of Hematology 1996	
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CK1		GERMOLEC et al., "Arsenic Induces Overexpression of Growth Factors in Human Keratinocytes", Toxicology and Applied Pharmacology, 141:301-318, 1996 ©Academic Press, Inc., 1996	
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CM1		KONIG et al., "Comparative Activity of Melarsoprol and Arsenic Trioxide in Chronic B-Cell Leukemia Lines", Blood 90(2):562-570, 1997. ©The American Society of Hematology 1997	
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CR1		NEUBAUER, "Arsenic Cancer: A Review", Arsenical Cancer, Arsenic Committee of the Medical Research Council, pp. 192-251, 1947	
CS1		REICHL et al., "Effect of Arsenic on Cellular Metabolism after Single or Repeated Injection in Guinea Pigs", Arch. Toxicol, Suppl. 13, p. 363-65, 1989	
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CW1		SOIGNET et al., "Complete Remission after Treatment of Acute Promyelocytic Leukemia with Arsenic Trioxide", J of Medicine 339:19, 1998. ©Massachusetts Medical Society 1998	
CX1		TRELEAVEN et al., "Arsenic and Ayurveda", Leukemia and Lymphoma, 10:343-345, 1993	
CY1		USP Dictionary of USAN and International Drug Names, United States Pharmacopeial Conventions, Inc., Rockville, MD p. 59, Nov. 1994.	
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CA2		XIANG et al., "60 Cases of Treating Acute Promyelocytic Leukemia by QINGDAI Tablet", Med. J. Chin. PLA 20(3):227-229, 1995	

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Sheet	4	of	5	Attorney Docket Number	CELLTH 3.0-003 CONT CONT XV

	CB2	YUAN et al., "Research on Traditional Methods for Purifying Realgar", Chung Yao Tung Pao, 13(8):23-26, 1988	
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	CD2	ZHANG et al., "Traditional Chinese and Western Medicine in the Treatment of 27 Patients with Malignant Lymphoma," Chinese J. Oncology, 10:61-62, 1988	
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	CF2	ZHANG et al., "Treatment of Acute Promyelocytic Leukemia with Intravenous Arsenic Trioxide", Chinese J. of Hematology 17(2) 1996	
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	CL2	SMORENBURG et al., "Randomized Cross-Over Evaluation of Body-Surface Area-Based Dosing Versus Flat-Fixed Dosing of Paclitaxel", J. Clin. Oncology, 21:197-202 (2003)	
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	CV2	SOIGNET et al., "Initial Clinical Study of a Novel Organic Arsenical, Melarsoprol, in Patients with Advanced Leukemia", Blood (W.B., Saunders, Philadelphia, PA), vol. 88, No. 10, p. 219A (ISSN: 0006-4971) (1996)	

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¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

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